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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/817,704	08/25/1997	ANTHONIUS J. SWAAK	P8214-7002	8580

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ARENT FOX KINTER PLOTKIN & KAHN, PLLC  
1050 CONNECTICUT AVENUE, N.W.  
SUITE 600  
WASHINGTON, DC 20036-5339

EXAMINER

EWOLDT, GERALD R

ART UNIT PAPER NUMBER

1644

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

08/817,704

Applicant(s)

SWAAK, ANTHONIUS J.

Examiner

G. R. Ewoldt, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 June 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 18,20,23-26 and 31-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18,20,23-26 and 31-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

#### DETAILED ACTION

1. Claims 18, 20, 23-26, 31-35, and newly added Claim 36 are currently pending in this application.
2. Applicant's amendment and remarks filed 6/04/04 are acknowledged.
3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:  
A person shall be entitled to a patent unless --  
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:  
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
5. Claims 18, 20, 23-26, and 32-35 stand rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Toshihide et al. (of record), for the reasons of record as set forth in the papers mailed 5/21/01, 1/25/02, 9/30/02, 4/04/03, and 12/04/03.

Briefly, the Toshihide et al. reference teaches the treatment of rheumatoid arthritis patients not treated with iron with recombinant human erythropoietin (Epo) for a period of three weeks. As, morning stiffness, loss of grip strength, painful joints, or swollen joints, comprise routine symptoms of rheumatoid arthritis, as well as the need for ameliorating erythrocyte sedimentation rates or C-reactive protein levels, the patients of the reference are inherently the patients of the instant claims and the reference teaches the limitations of the instant claims. Also note that the preliminary "identifying" step is also inherent in the method of the reference.

Applicant arguments, filed 6/04/04, have been fully considered but are not found persuasive. Applicant argues,

"As Applicant has also previously submitted, Toshihide et al. nowhere teach the treatment (claim 18) and amelioration (claim 20) of the symptoms that Pettersson et al. clearly teach are not treated by rHuEPO. Thus, Applicant continues to believe that

Toshihide et al. also can not anticipate the present claims.

Additionally, since steps of treating or ameliorating certain symptoms are not taught or suggested (but are taught against) by Pettersson et al. and Toshihide et al., Applicant continues to believe that the present claims would not have been obvious over either reference.

Applicant has also previously explained that the claims defining the method using "consisting of" language excludes patients also having iron added, as in Pettersson et al., and having blood collected, as in Toshihide et al."

It remains the Examiner's position that the reference teaches the same method steps, i.e., identifying patients and administering Epo, accordingly, the reference teaches the method of the instant claims. Additionally, the step of drawing blood in the reference does not separate the method of the reference from the method of the instant claims. Indeed, it is noted that the specification discloses the measurement of hemoglobin and ferritin levels (Table II), as well as erythrocyte sedimentation rates (Table III), all of which generally indicate the withdrawal of blood from the patients. Accordingly, if a method excluding blood withdrawal were patentably distinct, the instant specification could not support said method.

6. Claims 18, 20, 23-26, and 31-35 stand/are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Pettersson et al. (of record), for the reasons of record as set forth in the papers mailed 5/21/01, 1/25/02, 9/30/02, 4/04/03, and 12/04/03.

Briefly, the Pettersson et al. reference teaches the treatment of rheumatoid arthritis patients not treated with iron with recombinant human Epo for a period of 24 weeks. As, morning stiffness, loss of grip strength, painful joints, or swollen joints, comprise routine symptoms of rheumatoid arthritis, as well as the need for ameliorating an erythrocyte sedimentation rates or C-reactive protein levels, the patients of the reference are inherently the patients of the instant claims and the reference teaches the limitations of the instant claims. Also

note that the preliminary "identifying" step is also inherent in the method of the reference. Regarding the new limitation wherein the patient has not been treated with iron, note that only 10 of the 12 patients received supplemental iron (page 190, column 2).

Applicant arguments, filed 6/04/04, have been fully considered but are not found persuasive. Applicant argues, "Applicant have [sic] previously noted that Pettersson et al. teach that the Pettersson et al. treatment with rHuEPO resulted in "no significant change in our patients' joint status or in their [erythrocyte sedimentation rate] and [C-reactive protein] values" (emphases added). Thus, since Pettersson et al. discloses no significant change in these valves, Applicant continues to believe that Pettersson et al. can not anticipate the present claims, which require treatment (claim 18) and amelioration (claim 20) of symptoms left untreated by Pettersson et al."

It is the Examiner's position that the method of Pettersson et al. is still the method of the instant claims. It is curious that Applicant would argue that "significant change" would be required for the reference to anticipate the claimed invention. Employing the same standard to the claimed method would require a new rejection under the first paragraph of 35 U.S.C. 112 for lack of enablement given the disclosure that, while a "significant" decrease in the number of tender joints was observed, "The changes in other clinical parameters did not reach statistical significance due to the wide range of values and the small number of patients in the study."

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 18, 20, 23-26, 31-35, and newly added Claim 36, stand/are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the

application was filed, for the reasons of record as set forth in the paper mailed 12/04/03. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

- A) "A method of treating morning stiffness, loss of grip strength, painful joints, or swollen joints" (Claim 18).
- B) "A method of ameliorating an erythrocyte sedimentation rate or C-reactive protein level" (Claim 20).

Applicant arguments, filed 6/04/04, have been fully considered but are not found persuasive. Applicant argues, that the method of the instant claims is supported by the original "Use" claims as filed and the "exemplary method of pages 5-13 of the specification".

Assuming *arguendo*, that claims drawn to use of making a pharmaceutical preparation can now actually support claims drawn to a method of treatment, a review of the original claims shows that Claim 6, which recites morning stiffness, painful and swollen joints loss of grip strength, and pain, depends from independent Claim 5, which recites only rheumatoid arthritis. Accordingly, the broader method of the instant claims, encompassing any patient suffering from morning stiffness, loss of grip strength, painful joints, or swollen joints, or in need of ameliorating an erythrocyte sedimentation rate or C-reactive protein level, is not supported by the original claims. Regarding the "exemplary method of pages 5-13 of the specification", said method comprises a specific method of treating anemia of chronic disease (ACD) patients with a specific dosage and term of Epo administration. The disclosure of this single example cannot support the broad method of the instant claims.

9. The following are new grounds for rejection necessitated by Applicant's amendment.

10. Claims 18, 20, 23-26, 31-35, and newly added Claim 36, are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically, a method "wherein the patient has not been treated with iron".

Applicant indicates that support for this new limitation can be found at page 6, lines 6-7 of the specification.

A review of the specification discloses that the new limitation is found only as applying to the ACD patients disclosed in the specific example and not in the broad context of the instant claims.

11. Applicant's amendment or action (filing of new applications) necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.


13. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact

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the Electronic Business Center (EBC) at 866-217-9197 (toll-free).  
Additionally, the Technology Center receptionist can be reached  
at (571) 272-1600.

G.R. Ewoldt, Ph.D.  
Primary Examiner  
Technology Center 1600

  
8/9/04  
G.R. EWOLDT, PH.D.  
PRIMARY EXAMINER